

Claims.

1. A multi-component pharmaceutical dosage form suitable for retaining drug
5 substance which drug substance can be released to provide a controlled drug release profile in the gastrointestinal environment, characterised by a body having at least one cavity said cavity having a mouth opening and a film means connected to the body and closing the mouth opening.
2. A multi-component pharmaceutical dosage form according to claim 1 wherein
10 the body and /or the film means is made of materials such that the dosage form opens to release the drug substance in the GI environment.
3. A multi-component pharmaceutical dosage form according to claim 1 or claim 2 wherein the film means is connected to the body by a weld.
4. A multi-component pharmaceutical dosage form according to claim 3 wherein
15 the weld is an ultrasonic weld.
5. A multi-component pharmaceutical dosage form according to any one of claims 1 to 4 wherein the body comprises a first cavity and a second cavity therein, the first and second cavities having a first and a second mouth opening respectively, and a first and second film means connected to the body and closing the first and
20 second mouth openings.
6. A multi-component pharmaceutical dosage form according to claim 5 wherein the body comprises a base wall having an upper surface, the first cavity is defined by a skirt wall extending away from the upper surface of the said base wall to terminate in a rim defining the first mouth opening, the second cavity is defined by a skirt wall
25 extending away from the lower surface of said base wall to terminate in a rim defining the second mouth opening.
7. A multi-component pharmaceutical dosage form according to claim 6 wherein the first and/or second film means is a blister convex relative to the respective first and/or second cavity.
8. A multi-component pharmaceutical dosage form according to claim 6 wherein
30 the first and/or second film means is substantially planar relative to the first and/or second cavity.

9. A multi-component pharmaceutical dosage form according to any one of claims 1 to 5 wherein the body comprises a base wall having an upper surface, both the first and second cavities are defined by adjacent skirt walls extending from the upper surface of the said base wall to terminate in a rim defining the respective first and second mouth openings, the first and second film means connected to the body close both the first and second mouth openings.
10. A multi-component pharmaceutical dosage form according to claim 9 wherein the first and second cavities are adjacent and are divided from each other by a common skirt wall and the rims of their mouth openings are substantially coplanar.
11. A multi-component pharmaceutical dosage form according to any one of claims 1 to 4 wherein the film means comprises a first and second spaced apart film means defining a compartment suitable for retaining drug substance between said first and second film means.
12. A multi-component pharmaceutical dosage form according to claim 11 wherein the body comprises a base wall and a skirt wall extending therefrom to terminate in a rim defining the mouth opening, the mouth opening being closed by a first film means and a second film means is located under the said first film means to define an upper compartment between the first film means and the second film means.
13. A multi-component pharmaceutical dosage form according to claim 11 wherein the body comprises a base wall and a skirt wall extending therefrom to terminate in a rim defining the mouth opening, the first mouth opening being closed by a first film means and a second film means intermediate between the said first film means and the base wall to defines a first compartment between the first film means and the second film means and a second compartment between the second film means and the base wall.
14. A multi-component pharmaceutical dosage form according to claim 13 wherein the skirt wall has an internal ledge to which the second film means is connected.
15. A dosage form according to claim 1 comprising a first cavity having a mouth opening and a second body comprising a second cavity having a mouth opening which bodies are connected to each other around respective rims of each mouth opening and a film means separates the first cavity from the second cavity.

16. A dosage form according to claim 15 comprising a first body which comprises a first capsule shell defining a first cavity, having a first mouth opening and an opposite closed end,
a second body comprises a closure for the first mouth opening, and the second
5 body defines a second cavity having a second mouth opening facing toward the closed end of the first body when the second body is in place as a closure,
and the second mouth opening is closed by a film means, such that the film means is between the first and second cavities.
17. A dosage form according to claim 16 wherein the second body fits in a plug
10 and socket relationship into the first mouth opening.
18. A dosage form according to claim 16 or 17 which further comprises a second capsule shell defining a further cavity, having a further mouth opening and an opposite closed end,
and the second body comprises a closure for this further mouth opening of this
15 second capsule shell.
19. A dosage form according to claim 18 wherein the second body fits in a plug and socket relationship into the further mouth opening.
20. A dosage form according to claim 18 or 19 wherein the second body has a first surface which when the second body is in place as a closure for the first capsule shell
20 faces the closed end of the first capsule shell, and the second cavity is formed in the first surface, and an opposite surface which when the second body is in place as a closure for the first capsule shell faces the closed end of the second capsule shell.
21. A dosage form according to claim 18, 19 or 20 which comprises a linear arrangement of:
25 a first capsule shell defining a first cavity and having a first mouth opening,
a second body fitting in a plug and socket relationship into the first mouth opening, the second body having a second cavity therein having a second mouth opening which is closed by a film means, such that when the second body is so fitted into the first mouth opening the film means is between the first and second cavities,
30 and a further capsule shell defining a further cavity and having a further mouth opening into which the second body fits in plug and socket relationship.
22. A dosage form according to any one of claims 16 to 21 wherein a capsule shell is made of an immediate release polymer.

23. A dosage form according to claim 22 comprising two capsule shells both made of immediate release polymer.
24. A dosage form according to any one of the preceding claims wherein the film means closing the second mouth opening comprises an immediate release polymer.
- 5 25. A dosage form according to any one of claims 18 to 24 wherein the first and further capsule shells and the film means are immediate release polymer, and the first and second cavities enclose respective drug substances intended for immediate release.
26. A dosage form according to any one of the preceding claims wherein
- 10 component parts of the dosage form are connected together by a weld.
27. A dosage form according to any one of claims 22 to 26 wherein the immediate release polymer comprises Eudragit E100 or a blend thereof.
28. A dosage form according to any one of claims 24 to 27 wherein the immediate-release film means comprises hydroxyethyl cellulose, low molecular
- 15 weight hydroxypropylcellulose or low-substituted hydroxypropyl cellulose.
29. A dosage form according to any one of claims 24 to 28 wherein the film means is 20-300 micron thick.
30. A dosage form according to any one of the preceding claims coated with a polymeric coating.
- 20 31. A dosage form according to claim 30 wherein the coating comprises a delayed or pulsed release polymer which dissolves or is otherwise breached in an environment of defined pH.
32. A dosage form according to claim 31 wherein said polymer is an enteric polymer.
- 25 33. A dosage form according to any one of the preceding claims, substantially as hereinbefore described with reference to Fig. 1 or Fig. 10 or 11 of the accompanying drawings.
34. A dosage form according to any one of claims 1 to 14 wherein the body comprises a delayed release polymer and the film means comprises an
- 30 immediate release polymer.
35. A dosage form according to any one of claims 5 to 14 wherein the first film means comprises an immediate release polymer and the second film means comprises a delayed release polymer.

36. A dosage form according to any one of claims 34 or 35 wherein the delayed release polymer comprises a blend of Eudragit 4135F or Eudragit L100 or a blend thereof and the immediate release polymer comprises Eudragit E100 or a blend thereof.
- 5 37. A body suitable for use in a pharmaceutical dosage form according to any one of claims 1 to 36, comprising at least one cavity having a mouth opening and adapted for connecting a polymer film thereto.
36. 38. A body according to claim 37 comprising a delayed release polymer or an immediate release polymer.
- 10 39. A body according to claim 38 wherein the polymer comprises a delayed release polymer.
40. A body according to claim 39 wherein the delayed release polymer comprises Eudragit 4135F.
41. A process for the preparation of a dosage form according to any one of claims 15 1 to 36, optionally wherein the body comprises two cavities, comprising the following steps:
1. Forming a body e.g. by injection moulding of a suitable polymer
 2. Optionally applying a polymer coat to the body.
 3. Filling a first cavity with drug substance
 - 20 4. Closing the first cavity with a film means
 5. Filling a second cavity with the same or different drug substance
 6. Closing the second cavity.